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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,319	12/01/2005	Edward Duncan Blair	PG4871USw	9292

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,319	BLAIR ET AL.	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,17,18,23-25,27 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13, 17-18, 23-25, 27 and 29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the preliminary amendment dated 1/14/2005, amending all pending claims. Claims 14-16, 19-22, 26 and 28 have been cancelled. No claims are newly added. Claims 1-13, 17, 18, 23-25, 27 and 29 are pending in the application. Applicant should note that claim 17 is missing a status identifier.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 and 17-18, drawn to a transgenic mouse whose genome comprises a polynucleotide encoding human ICAM-1 domains D1 and D2.

Group II, claim(s) 23-25, drawn to an isolated polynucleotide encoding human ICAM-1 domains D1 and D2 and a regulatory sequence capable of directing expression of said polynucleotide in the murine respiratory tract; a vector comprising said polynucleotide and a cells transfected with said polynucleotide.

Group III, claim(s) 27, drawn to a method of producing a transgenic mouse comprising introducing into ES cells a polynucleotide encoding human ICAM-1 domains D1 and D2 and a regulatory sequence capable of directing expression of said polynucleotide in the murine respiratory tract.

Group IV, claim(s) 29, drawn to a method of screening test agents in the treatment of a condition associated with major group HRV infection comprising administering a test agent to a transgenic mouse whose genome comprises a polynucleotide encoding human ICAM-1 domains D1 and D2.

2. Group I claims encompass a plurality of distinct inventions exemplified by structurally distinct transgenic mice whose genomes comprise distinct nucleic acid sequences. Because the nucleic acids have distinct structural sequences, not commonly shared, the sequences and the transgenic mice encoding said sequences lack unity of invention. Applicant is required to choose

a single, specific transgenic mouse with the corresponding transgene SEQ ID NO, should the invention of Groups I be elected for examination. While nucleic acids and their correspondingly encoded polypeptides are also structurally distinct, under the rules for unity of invention, they are examined together. However, said rule does not apply to distinct chimeric sequences encoding distinct polypeptides. Hence the claims encompass an improper Markush Grouping, lacking unity of invention (In *re* *>*Harnisch*<, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). This is not a species restriction requirement.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. According to PCT Rule 13.2, unity of invention exists only when a shared same or corresponding special technical feature is a contribution over the prior art. The technical feature, which is shared by Groups I-V, is a polynucleotide encoding human ICAM-1 domains D1 and D2. Groups I-IV do not share a special technical feature over the art because Staunton et al. (J. Immunol. 148:3271-3274; 1992; of record), teach polynucleotides encoding human ICAM-1 domains D1 and D2 (Abstract), in addition to human-mouse chimeric ICAM-1 (Figure 3). Therefore an invention of a composition or transgenic mice comprising a polynucleotide encoding human ICAM-1 domains D1 and D2 fails to make a contribution over the prior art and there is no special technical feature between Groups I-IV.

Further, the search and examination of the composition and method described in inventions of Groups I-IV for prior art and patentability are not coextensive, as each invention is directed to a distinct goal, and employs particulars not required for the other. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-IV do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specific regulatory sequence, as recited in claim 6. The CMV, SV40, hSPC or CC10 are each distinct regulatory sequences, having no substantially shared common technical features, where each is not required for the other, requiring non-coextensive search and examination of their respective subject matter.

A specific mode for gene transfer, as recited in claim 27. The electroporation/lipofection and retroviral gene transfer are distinct modes of gene transfer, having no substantially shared common technical features, where each is not required for the other, requiring non-coextensive search and examination of their respective subject matter.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 6 and 27, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 1-6, and 27.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As the technical features linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since the acyl chains, headgroups, lipids, nucleic acids and cell types do not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst William Phillips, whose telephone number is **(571) 272-0548**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER